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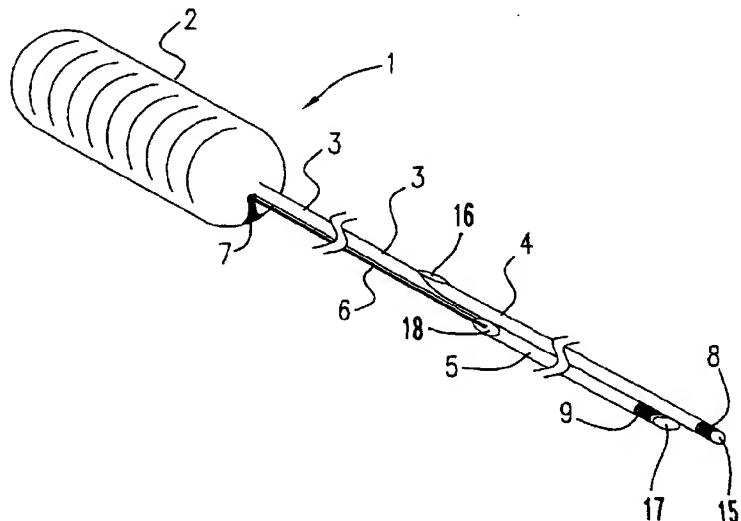
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(54) Title: A GUIDEWIRE POSITIONING DEVICE



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(57) **Abstract:** A device (1) for facilitating the delivery of components along guidewires to branches of a tubular system. The device has particular application for the percutaneous treatment of vascular and non-vascular disease, and more specifically for balloon angioplasty or the deployment of stents. The device includes a shaft (3) and two or more guidewire lumina (4, 5) interconnected to and parallel to one another, each lumen having an open distal end and an open proximal end on the shaft (3). In a preferred form the device includes a manipulation aid (2) at a proximal end of the shaft (3) which can engage one of the guidewires (6), and which facilitates rotation of the device. The invention also includes a method of positioning guidewires for the subsequent delivery of components such as stents to lesions at a bifurcation, using the guidewire positioning device.

A GUIDEWIRES POSITIONING DEVICE

Technical Field

5 This invention relates to a method and device for facilitating the delivery of components along guidewires to branches of a tubular system. It has particular application for the percutaneous treatment of vascular and non-vascular disease, and in particular in the use of balloon angioplasty and for the deployment of balloon-expanded or self-expanding stents.

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Background

15 Balloon angioplasty or deployment of stents for lesions at a bifurcation may require that the component (balloon angioplasty or stent) be advanced into position over two guidewires, each of which is positioned in a separate downstream branch vessel. It is important that, when the guidewires are positioned prior to the component delivery, the guidewires do not become entangled or wrapped around each other.

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 It is an object of the present invention to provide a guidewire positioning device, method of positioning guidewires and method of delivering components to branch vessels which reduces or overcomes the abovementioned problem, or which at least provides the public with

25 a useful alternative.

 It is to be appreciated, however, that the invention is not restricted to application for the treatment or management of vascular disease. It could also have application in non-vascular disease in

30 situations where components need to be positioned in branched vessels along guidewires, or indeed in the delivery of components to branched vessels of any tubular system.

Other objects of the invention may become apparent from the following description which is included by way of example only.

Summary of the Invention

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According to one aspect of the present invention there is provided a guidewire positioning device for facilitating the delivery of components along guidewires to two or more branches of a tubular system, said device including a shaft and two or more guidewire lumina interconnected to and parallel to one another, each said lumen having an open distal end and an open proximal end on said shaft.

10 Preferably, the tubular system may be a vascular system and the device may be adapted for facilitating the delivery of components used 15 in the management of vascular disease.

Preferably, the device may be adapted for the delivery of stents to lesions at a bifurcation.

20 According to a further aspect of the present invention there is provided a method of positioning guidewires for the delivery of components to two or more branches of a tubular system the method including the steps of:

25 - engaging a first guidewire through a first guidewire lumen of a guidewire positioning device, before or after advancing the first guidewire along the tubular system and into a first branch;

advancing one or more further guidewires along one or more further guidewire lumen, interconnected to and parallel to the first guidewire lumen, of the 30 guidewire positioning device, to a distal end of said further guidewire lumen;

- advancing the guidewire positioning device, with the engaged further guidewire or guidewires, along the first guidewire by means of a shaft of the guidewire positioning device, until said distal end of the or each further guidewire lumen is adjacent the branching of the tubular system;
- rotating the shaft of the guidewire positioning device so that the distal end of the or each further guidewire lumen is adjacent a second branch of the tubular system; and
- advancing the, or one of the, further guidewires into the second branch.

According to a further aspect of the present invention there is provided a method of treating a lesion or lesions at a bifurcation in a blood vessel, said method including the steps of:

- engaging a first guidewire on a first guidewire lumen of a guidewire positioning device, before or after advancing the first guidewire along the blood vessel and into one down stream branch vessel;
- advancing a second guidewire to a distal end of a second guidewire lumen, interconnected to and parallel to the first guidewire lumen, of the guidewire positioning device;
- securing the second guidewire in relation to the guidewire positioning device;
- advancing the guidewire positioning device, with the secured second guidewire, along the first guidewire by means of a shaft of the guidewire positioning device until the distal end of the second guidewire lumen is at the bifurcation;

- rotating the guidewire positioning device, if necessary, to align the distal end of the second guidewire lumen with the second branch vessel;
- advancing the second guidewire into the second branch vessel;
- withdrawing the guidewire positioning device along both the first and second guidewires; and
- advancing a stent or angioplasty balloon along one or each guidewire to treat a lesion at the bifurcation.

10

Brief Description of the Drawings

15 Figure 1: Shows a longitudinal section of a guidewire positioning device of the invention in one preferred form;

20 Figure 2: shows a perspective view of the device of Figure 1 with a guidewire engaged in the second lumen;

25 Figure 3: shows an enlarged longitudinal section of the distal end of the device of Figure 2;

30 Figure 4: shows longitudinal sections of alternative configurations of the joins between the shaft and the two guidewire lumina of a guidewire positioning device of the invention; and

35 Figure 5: shows a cross section through the manipulation aid of the device of Figures 1 and 2, in one preferred form.

Detailed Description of the Invention

The invention will now be described by reference to the preferred embodiment for use in the management of vascular disease. However, 5 as indicated above, it is to be appreciated that the invention is not restricted to such an application, there being other applications both in medicine and elsewhere, where the accurate positioning of components in vessels, tubes or pipes including bifurcations or multiple branches is important but difficult, and where the use of guidewires would be 10 helpful providing that the risk of wrapping or entanglement of the guidewires could be avoided.

With reference to Figures 1 and 2, a guidewire positioning device 1 of the invention has two guidewire lumen which are interconnected to 15 one another and parallel. The first guidewire lumen 4 has an open distal end 15 and an open proximal end 16. Similarly, the second guidewire lumen 5 has an open distal end 17 and open proximal 18. A radio- opaque marker 8, 9 may be positioned at or close to the distal end 15, 17 so that the position of the distal ends may be determined through 20 fluoroscopy.

The second guidewire lumen 5 may have a distal end 17 a short distance (approximately 10mm) proximal to the distal end 15 of the first guidewire lumen 4. Alternatively, the second guidewire lumen 5 might 25 extend to the distal end 15 of the first guidewire lumen 4, or it may end distally a considerable distance more than 10mm from the distal end 15 of the first guidewire lumen 4.

The distal end 17 of the second guidewire lumen 5 may have an 30 oblique bevelled shape 10, as best seen in Figure 3. This shape aids advancement of the guidewire positioning device 1 into position in the vessel, and also aids advancement of a guidewire from the second

guidewire lumen 5 into a branch vessel. The radio-opaque marker 9 at or close to the distal end 17 of the second guidewire lumen 5 may have a symmetrical or asymmetrical configuration. An asymmetrical shape, as shown in Figure 3, may aid orientation of the second guidewire 5 lumen 5 in the vessel under fluoroscopy.

Proximally, the guidewire lumen may have a double over-the-wire, double monorail, or combination over-the-wire/monorail configuration. A double monorail configuration would require a separate proximal catheter shaft (as in Figures 1 and 2). At the proximal end of this shaft 3 there may be a longitudinally enlarged hub 2, or manipulation aid, to aid catheter manipulation. This hub 2 may have a longitudinal recessed groove 7 into which a guidewire may be positioned, as shown in Figures 2 and 5. Slotting a guidewire 6 in place 15 in this groove 7 holds the guidewire in position in relation to the guidewire positioning device, as the device is advanced, withdrawn or rotated to manipulate the distal end of the device. Figure 5 shows that this groove 7 may include ribbing 19 or other means, to grip the guidewire 6.

20

Whilst the invention is described above by reference to the device including two parallel lumina, it should be appreciated that one or more additional parallel lumina may be included for use in applications where a parent vessel or tube branches into more than two branches or 25 where more than one separate component is required to be delivered to one particular branch.

Figures 1 and 3 show a guidewire positioning device 1 of the invention in a monorail version. The proximal ends 16, 18 of the 30 guidewire lumina 4, 5 are shown off set in this embodiment, with the proximal end 16 of the first guidewire lumen 15 proximal of the proximal end 18 of the second guidewire lumen 5, consistent with the

embodiment of Figure 4B. The embodiment of Figure 4A shows the two proximal ends 16, 18 at the same proximal position in relation to the shaft 3. Figure 4 also shows of the interconnection between the shaft 3 and the lumina 4, 5. In a preferred form the guidewire 5 positioning device of the invention, including the hub 2, shaft 3 and lumina 4, 5 may be integrally formed from plastics material.

The method of use of the device of the present invention will now be described.

10

If a double monorail device is used, one method of use, after deployment of the guide catheter, is to advance a first guidewire via the first guidewire lumen 4 and along the guide catheter, across the bifurcation lesion and into one downstream branch vessel. Alternatively 15 the first guidewire may be advanced along the guide catheter first and the first guidewire lumen then engaged on the first guidewire via its proximal end. A second guidewire is then positioned in the second guidewire lumen 5 of the device and advanced until the distal end of the guidewire is close to or adjacent the distal end 17 of the second 20 guidewire lumen 5. The proximal portion of the second guidewire is then slotted into the recessed groove 7 in the hub 2 at the proximal end of the catheter shaft 3, to hold that guidewire in position as the guidewire positioning device 1 is subsequently manipulated.

25 The guidewire positioning device 1 and the second guidewire are then advanced as a unit along the first guidewire already positioned in the vessel. The guidewire positioning device 1 is advanced until the distal end 15 of the first guidewire lumen 4 is just beyond the bifurcation and the distal end 17 of the second guidewire lumen 5 is 30 almost at the bifurcation. It will be appreciated that in an embodiment of the device in which the distal ends of the guidewire lumina are

adjacent one another then both will be positioned substantially at the bifurcation.

The guidewire positioning device 1 is then rotated by

5 manipulation of the hub 2 so that the bevelled, marked distal end 17 of the second guidewire lumen 5 is aligned with the other branch vessel which does not yet have a guidewire. The second guidewire is then released from the hub and steered into the second branched vessel.

10 Once the second guidewire is in position the guidewire positioning device may be withdrawn, with both guidewires kept in position, one in each downstream branch vessel. Angioplasty balloons or stents can then be advanced over one or both guidewires to treat the lesion in the knowledge that the guidewires are not entangled or wrapped around each other.

15

Thus, the guidewire positioning device 1 of the invention provides a relatively simple device which can be used to facilitate the delivery of guidewires to branched regions of a tubular system, such as blood vessels, to enable the delivery of components required in those 20 branches along the guidewires, without the risk of complications associated with multiple guidewires becoming wrapped or entangled with one another.

Where in the foregoing description reference has been made to

25 specific components or integers of the invention having known equivalents then such equivalents are herein incorporated as if individually set forth.

Although this invention has been described by way of example

30 and with reference to possible embodiments thereof it is to be understood that modifications or improvements may be made thereto without departing from the scope or spirit of the invention.

CLAIMS

1. A guidewire positioning device for facilitating the delivery of components along guidewires to two or more branches of a tubular system, said device including a shaft and two or more guidewire lumina interconnected to and parallel to one another, each said lumen having an open distal end and an open proximal end on said shaft.
- 10 2. A guidewire positioning device according to claim 1 wherein the tubular system is a vascular system and the device is adapted for facilitating the delivery of components used in the management of vascular disease.
- 15 3. A guidewire positioning device according to claim 2 for the delivery of stents to lesions at a bifurcation.
4. A guidewire positioning device according to any one of claims 1 to 3 including a first guidewire lumen and a second guidewire lumen.
- 20 5. A guidewire positioning device according to claim 4 wherein the distal end of the first guidewire lumen is distal of the distal end of the second guidewire lumen.
- 25 6. A guidewire positioning device according to any one of claims 1 to 5 wherein the distal end of the second guidewire lumen has an oblique bevelled shape.
- 30 7. A guidewire positioning device according to claim 6 wherein the distal end of the first guidewire lumen has an oblique bevelled shape oppositely angled to that of the second guidewire lumen.

8. A guidewire positioning device according to any one of claims 4 to 7 wherein the proximal end of the first guidewire lumen is proximal of the proximal end of the second guidewire lumen.
- 5 9. A guidewire positioning device according to any one of claims 4 to 8 further including a manipulation aid at a proximal end of said shaft.
- 10 10. A guidewire positioning device according to claim 9 wherein the manipulation aid further includes a guidewire engagement means.
11. A guidewire positioning device according to either claim 9 or claim 10 wherein the manipulation aid is a longitudinally enlarged hub.
- 15 12. A guidewire positioning device according to claim 11 wherein the guidewire engagement means is a longitudinal slot in said hub.
13. A guidewire positioning device according to any one of claims 4 to 12 wherein each guidewire lumen includes a radio-opaque marker at or adjacent its distal end.
- 20 14. A guidewire positioning device according to claim 13 wherein the radio-opaque marker on either or both guidewire lumen is asymmetrical.
- 25 15. A guidewire positioning device according to any one of claims 1 to 14 wherein the device is integrally formed from plastics material.

16. A method of positioning guidewires for the delivery of components to two or more branches of a tubular system, the method including the steps of:

- engaging a first guidewire on a first guidewire lumen of a guidewire positioning device, before or after advancing the first guidewire along the tubular system and into a first branch;
- advancing one or more further guidewires along one or more further guidewire lumen, interconnected to and parallel to the first guidewire lumen, of the guidewire positioning device, to a distal end of said further guidewire lumen;
- advancing the guidewire positioning device, with the engaged further guidewire or guidewires, along the first guidewire by means of a shaft of the guidewire positioning device, until said distal end of the or each further guidewire lumen is adjacent the branching of the tubular system;
- rotating the shaft of the guidewire positioning device so that the distal end of the or each further guidewire lumen is adjacent a second branch of the tubular system; and
- advancing the, or one of the, further guidewires into the second branch.

17. A method according to claim 16 wherein the guidewire positioning device further includes a manipulating aid, and rotation of the shaft is facilitated by this manipulating aid.

18. A method according to either claim 16 or claim 17 further including securing a proximal end of the or each further guidewire

to the guidewire positioning device prior to advancing the guidewire positioning device along the first guidewire.

19. A method according to any one of claims 16 to 18 further including the step of monitoring the position of the distal end of the or each further guidewire lumen in the tubular system by having identification means at this distal end.
20. A method according to claim 19 wherein the identifying means includes a radio-opaque marker on said distal end.
21. A method of treating a lesion of lesions at a bifurcation in a blood vessel, said method including the steps of:
 - engaging a first guidewire on a first guidewire lumen of a guidewire positioning device, before or after advancing the first guidewire along the blood vessel and into one down stream branch vessel;
 - advancing a second guidewire to a distal end of a second guidewire lumen, interconnected to and parallel to the first guidewire lumen, of the guidewire positioning device;
 - securing the second guidewire in relation to the guidewire positioning device;
 - advancing the guidewire positioning device, with the secured second guidewire, along the first guidewire by means of a shaft of the guidewire positioning device until the distal end of the second guidewire lumen is at the bifurcation;
 - rotating the guidewire positioning device, if necessary, to align the distal end of the second guidewire lumen with the second branch vessel;

- advancing the second guidewire into the second branch vessel;
- withdrawing the guidewire positioning device along both the first and second guidewires; and
- 5 - advancing a stent or angioplasty balloon along one or each guidewire to treat a lesion at the bifurcation.

22. A method according to claim 21 wherein the first guidewire lumen has a distal end distal of the distal end of the second guidewire lumen, and wherein the guidewire positioning device is advanced along the blood vessel until the distal end of the first guidewire lumen is positioned within the first branch vessel.

10

23. A method according to either claim 21 or claim 22 further including monitoring the position of distal end of the second guidewire lumen by having identification means at this distal end.

15

24. A method according to claim 23 further including monitoring the position of the distal end of the first guidewire lumen having identification means at this distal end.

20

25. A method according to either claim 23 or claim 24 wherein the or each identification means includes a radio-opaque marker, and the positions are monitored by fluoroscopy.

25

26. A guidewire positioning device substantially as herein described and with reference with to the accompanying drawings.

27. A method of positioning guidewires for the delivery of components to two or more branches of a tubular system substantially as herein described and with reference to the accompanying drawings.

30

28. A method of treating a vascular lesion at a bifurcation using a guidewire positioning device according to any one of claims 1-15.

5

29. A method of treating a vascular lesion at a bifurcation substantially as herein described and with reference to the accompanying drawings.

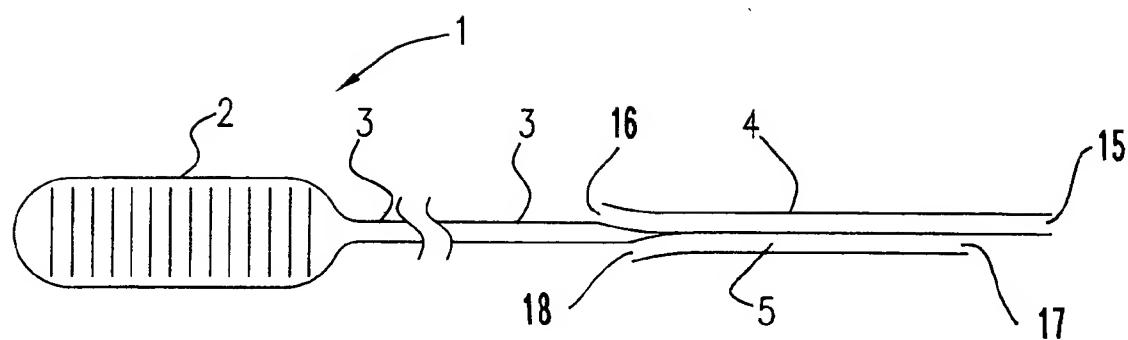


FIGURE 1

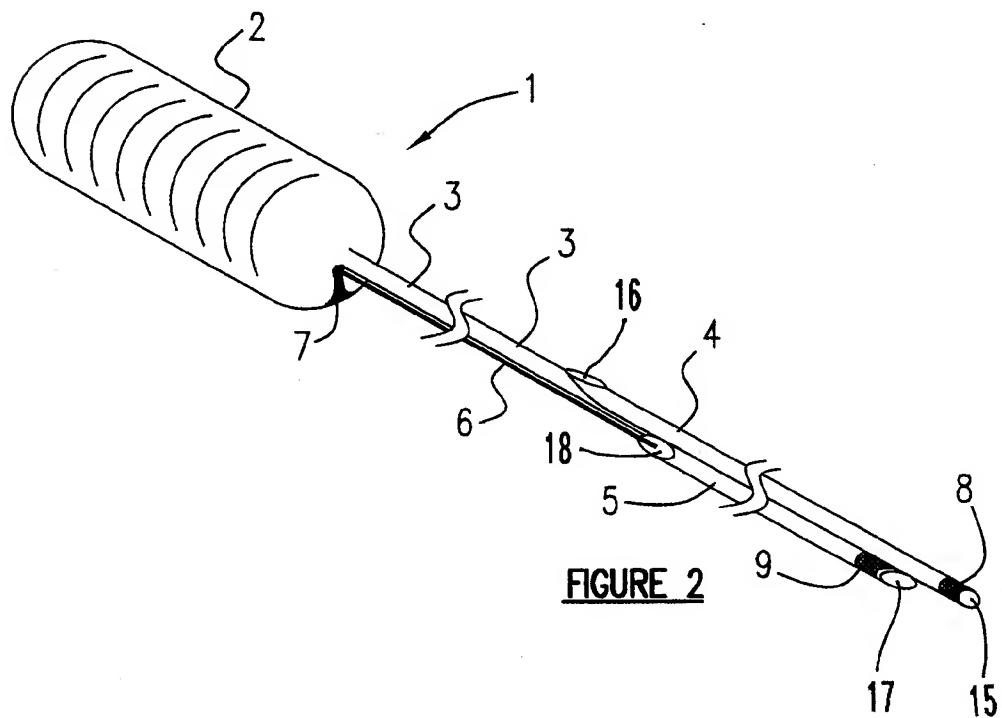


FIGURE 2

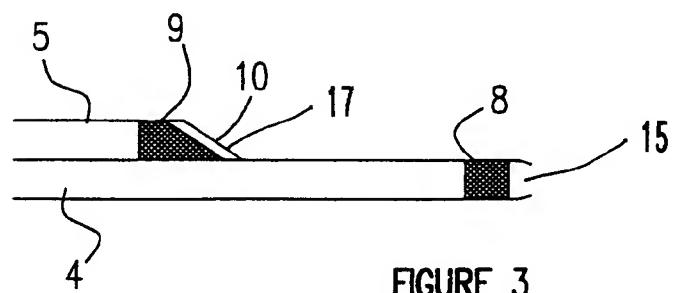


FIGURE 3

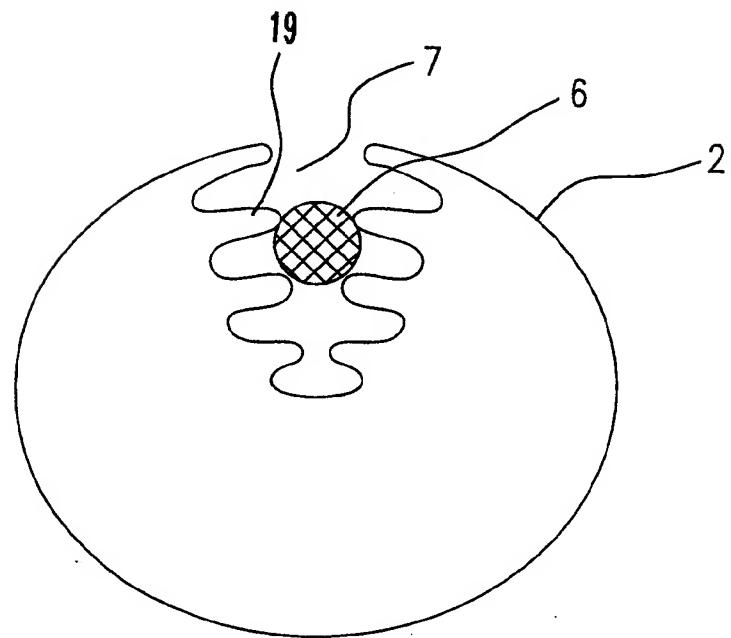
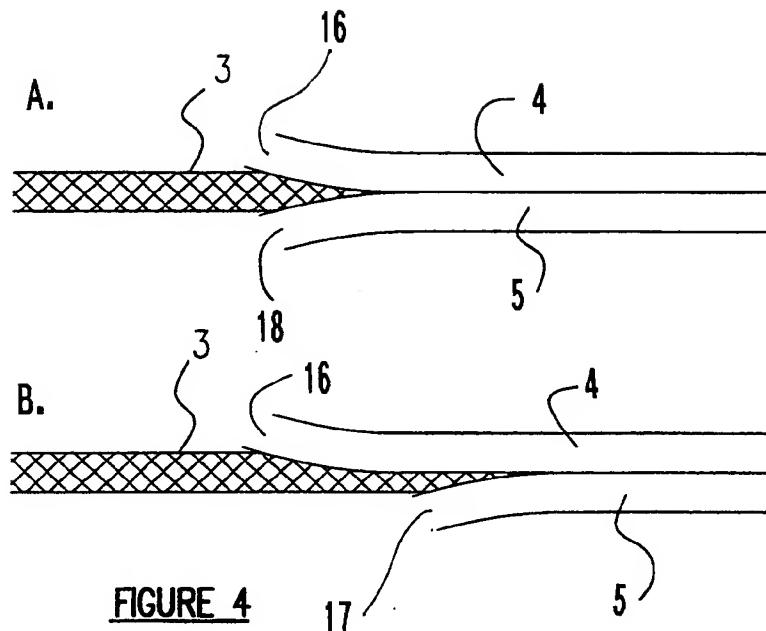


FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ00/00210

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. 7: A61M 25/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 897700 A (ADVANCED CARDIOVASCULAR SYSTEMS) 24 February 2000 column 20 lines 3 to 30 column 22 line 54 to column 23 line 16	1-25, 28
X	WO 99/34749 A (WEBSTER) 15 July 1999 Page 7 lines 6 to 11	1-9, 11, 15
X	US 5749825 A (FISCHELL et al.) 12 May 1998 Column 2 lines 34 to 48	1-5, 8, 9, 11, 15
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 3 January 2000	Date of mailing of the international search report 11 January 2001	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer  DAVID MELHUISH Telephone No : (02) 6283 2426	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/NZ00/00210

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member
EP 897700	JP 11057019
WO 99/34749	AU 20785/99
US 5749825	

END OF ANNEX